RyMed TECHNOLOGIES, INC.
From the Office of the President

RYMED SPECTRUM OF PROTECTION

**InVision-Plus®** with **Neutral Advantage™ technology**

December 3, 2009

**Dear CDC and Guidelines for the Prevention of Intravascular Catheter-Related Infections Writing Committee:**

Thank you for the investment of time and effort into revising the 2002 Guidelines for the Prevention of Intravascular Catheter-Related Infections. This is a tremendous and much appreciated undertaking. I am providing comments and suggestions relative to the Needleless Intravascular Catheter Systems Recommendations 5 and 6 appearing on Page 48, Line 1077-1078, in addition to the Background section that follows.

**Recommendation 5**

**5. Use a needleless system to access IV tubing. Category IC**

OSHA guidelines and directives from 1991 and 1999 mandate the use of needleless systems over needle-based systems to promote healthcare worker safety and avoid accidental needle stick injuries and potential blood-borne pathogen exposure. A distinction should be noted, however, about the term "needleless systems." True needleless systems should refer universally to those that are not compatible with and do not accept steel needles in any way to successfully access the fluid pathway and deliver fluids. Many currently marketed needleless I.V. connectors are steel needle-compatible, while others are not. "Blunt cannula split-septum" product lines introduced to the market in the early 1990's (Baxter *InterLink*®, Hospira *LifeShield*®), "luer-activated split- septum" product introduced in the early 2000's (Becton Dickinson *Q-Syte*™), and mechanical valves (CareFusion *SmartSite*® and *SmartSite Plus®)* introduced to the market in the early 1990's and early 2000's respectively, are viewed to be non-compliant due to the fact that steel needles can still be used to access the patient's fluid pathway, increasing the potential for blood-borne pathogen exposure through accidental needle stick injuries. These devices could be out of compliance with the Category IC system rating. **The safest needleless I.V. connector systems as it pertains to the OSHA guidelines are accessed with standard luer syringes, blood collection devices and I.V. sets, and are designed so that steel needles cannot be used to deliver or aspirate patients fluids from vascular access catheters.**

**Recommendation 6**

**6. When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection, [336-339]. Category II**

The terms "split-septum valve" and "mechanical valve" should be avoided in Recommendation 6. The current standard of care in IV access is to use a standard luer-lock syringe, blood collection device or I.V. line activated needleless I.V. connector as described earlier. The marketplace generally associates a "split septum" device with the Baxter *Interlink*® or Hospira *LifeShield*®. All currently marketed standard luer-lock activated needleless I.V. connectors are generally considered to be mechanical valves. (A sub-classification exists among devices referred to as "positive pressure displacement mechanical valves," or PPMVs. The 2008 IDSA/SHEA *Compendium of Strategies to Prevent Central Line-Associated Bloodstream Infections in Acute Care Hospitals* provided a recommendation against the routine use of PPMVs due to their increased risk of infection. The term "split septum valve," using references 336 (**Rupp**), 337 (**Salgado**), and 339 (**Field**), refer directly to documented use of the Baxter *Interlink*®. Reference 338 (**Maragakis**) documents use of the ICU Medical, Inc. CLAVE® I.V. Connector, which is pictured and described as a "mechanical valve." The *Maragakis* reference does not support the recommendation. Furthermore, the referenced

articles define specifically what is meant by the term "split-septum." *Maragakis* defines a "split septum" I.V. connector as having "a slit in the access surface diaphragm that is accessed using a compatible blunt cannula injector." *Rupp* similarly defines "split septum" devices as having "a pre-pierced diaphragm that is accessed via a blunt cannula." *Field* provides no written definition of a "split septum" device as described above, although the Baxter *Interlink*® IV Access System is mentioned and pictured. *Maragakis* defines mechanical valves as "intravenous access ports…that allow the use of syringe tips to directly access the port without needles or special injectors (Figure 1)." *Rupp* describes three basic design types to be "split-septum" I.V. connectors, luer-activated valves, and positive displacement luer-activated valves. However, some prominent manufacturers of luer-lock activated devices, i.e. "mechanical valves," currently market their products as "split-septum" devices. This has created significant and widespread marketplace confusion about all needleless I.V. connectors and which category they fall into.

**Example #1 – BD Q-Syte™ Luer Access Split Septum**

The BD *Q-Syte*™ Luer Access Split Septum is a standard luer-lock activated device, i.e. it is a mechanical valve. However, the manufacturer knowingly and actively markets the Q-Syte™ as a "split-septum" valve.

See the following website links:

http://www.bd.com/infusion/products/ivaccess/

http://www.bd.com/infusion/products/ivaccess/qsyte.asp

The manufacturer of the Q-Syte™ also uses references to published data in advertisements to represent to the marketplace that efficacy associated with the "split-septum" Baxter *Interlink*® IV Access System should relate directly to that of the Becton-Dickinson *Q-Syte*™ Luer Access Split Septum.

http://www.bd.com/infusion/products/ivaccess/

> "Patients are three times more likely, on average, to develop a CR-BSI with the use of mechanical valves vs. split septum needleless access system.[1,2]"
>
> "A split-septum needleless access system has 64%-70% lower CR-BSI rates than mechanical valves.[1,2]"

[1] Rupp ME, Sholtz LA, Jourdan DR, et al. Outbreak of bloodstream infection temporally associated with the use of an intravascular needleless valve. CID. 2007;44:1408-1414.

[2] Salgado CD, Chinnes L, Paczesny TH, Cantey JR. Increased rate of catheter-related bloodstream infection associated with the use of a needleless mechanical valve device at a long-term acute care hospital. ICHE 2007;28:864-688.

The manufacturer's promotion of the *Q-Syte*™ product line as a "split-septum" when it is a (luer-activated) mechanical valve confuses the marketplace not only about the category to which it belongs but also the definition of the categories themselves and the classification of other devices. The use of the term "split septum valve" and "mechanical valve" in Recommendation 6 illustrates and perpetuates the marketplace's confusion.

**Example 2 – ICU Medical, Inc. CLAVE® and MicroClave® I.V. Connectors**

The CLAVE® and MicroClave® connectors are standard luer-lock activated devices, i.e. mechanical valves. In fact, *Maragakis* directly refers to the CLAVE® as a mechanical valve (ICHE January 2006, Vol. 27, No. 1, page 68, Figure 1.) However, the manufacturer knowingly and actively markets the CLAVE® and MicroClave® using "split septum" seal or "reverse split-septum" terminology. Please see inside cover

advertisements in AJIC, August 2009, Volume 37, Number 6, and JAVA, Volume 14, Number 3, Fall 2009, and others, in addition to the websites below.

http://www.icumed.com/Docs-Clave/M1-1194_CLAVE_BrochFolder.pdf

http://www.icumed.com/Docs-MicroClave/M1-1113-MicroClave-Brochure-Rev5.pdf

The manufacturer's promotion of the CLAVE® and MicroClave® as "split-septum" devices when they are (luer-activated) mechanical valves confuse the marketplace not only about the category to which they belong, but also the definition of the categories themselves and the classification of other devices. The use of the term "split-septum valve" and "mechanical valve" in Recommendation 6 illustrates and perpetuates the marketplace's confusion.

Finally, use of the term "mechanical valve" in Recommendation 6, inasmuch as it is a recommendation against any device that is considered mechanical, amounts to an indictment of any new technology needleless I.V. connectors that are standard "luer-activated". Furthermore, use of the term "mechanical valve" under appreciates and negatively associates new standard luer-activated with fail-safe engineering design technology with older positive-pressure displacement mechanical valves (PPMV) that have been associated with increased risk of infection.

RyMed Technologies, Inc. manufactures the ***InVision-Plus®*** with ***Neutral Advantage™*** technology. It is a standard luer-activated valve. The ***InVision-Plus®*** possesses many favorable design elements that are functionally similar to the general meaning of "split-septum" devices. Conversely, it does not contain any of the features, e.g. an anti-reflux valve or moving mechanical parts in the fluid pathway that are known to complicate flushing and promote biofilm potential, that are commonly attributed to mechanical valves in general, or PPMVs that have been associated with infection risk. Therefore, it does not fit neatly into either a "split-septum" or a "mechanical valve" category when these terms are used. The ***InVision-Plus®*** is a hybrid standard luer-activated design that is completely steel needle-incompatible to comply with OSHA guidelines. It consists of a tightly closed and compressed septum design that is, in fact, pre-pierced. The ***InVision-Plus®*** remains tightly sealed and is always under a state of compression when not in use. It has a smooth, septum surface that can be easily and effectively swabbed and *in-vitro* comparison studies have demonstrated >99.9% effectiveness with a 3 to 5 rotation swabbing procedure. This "septum seal integrity" is a critical feature for the achievement of the new January 1, 2010 Joint Commission National Patient Safety Goal Guidelines for Hospital Accreditation Program NPSG.07.04.01 to use a standardized protocol t disinfect catheter hubs and needleless I.V. connectors before accessing. The ***InVision-Plus®*** also consists of a second independent microbial barrier to further protect the fluid pathway against downstream contamination. The ***InVision-Plus®*** is engineered with a built-in blunt cannula component inside the housing. This comprises the fluid pathway which is straight-through, has zero dead space, no obstructions or moving mechanical parts, and can be effectively flushed with only 1 mL 0.9% normal saline. The ***InVision-Plus®*** also has "zero fluid displacement" and, therefore, does not need to be clamped either prior to disconnecting, as in negative fluid displacement mechanical valves and "split-septum" devices, or unclamped prior to connecting, as in positive pressure displacement mechanical valves. Also, the ***InVision-Plus®*** can be flushed with 0.9% normal saline only, per institutional protocol, thereby reducing the use of heparin and the risk for heparin-induced thrombocytopenia (HIT). Split-septum with blunt cannula devices, and all negative fluid displacement devices, should not be flushed with normal saline only. Since Biofilm is the precursor to CR-BSI, a multi-facet approach such as developed by RyMed which addresses both the enhancement of nursing swabbing and flushing procedure success and at the same time minimizes fibrin adhesion associated with repetitive blood reflux into the catheter lumen during either connection to or disconnection from most needleless I.V. connectors, offers a systematic approach that is much more robust than just needleless connection.

The **InVision-Plus®**, unlike many other standard luer-activated valves and PPMVs, has not been associated with increased infection risk in any published articles or abstracts. In fact, RyMed's ***InVision-Plus®*** is cited in the December 2007 issue of *JAVA,* Volume 12, Number 4, as a key intraluminal catheter fluid pathway component in the catheter care and maintenance bundle contributing to zero CR-BSI at Sutter Roseville Medical Center, Roseville, CA for 15 months. The Sutter Medical Center is currently approaching 4 years (as of December 31, 2009) of zero CR-BSI rates. The intravenous route of administration is the primary

therapeutic route used in patient care today. The needleless I.V. connector is the "gatekeeper" of the intraluminal catheter fluid pathway. When 16 different manufactured needleless I.V. connectors which require different nursing care and are referred to differently in the literature, it is inappropriate to generalize them all as "split-septum" or "mechanical valves". Doing so constitutes a disservice to healthcare providers which actively seek the most efficacious technologies to minimize and prevent *catheter-related bloodstream infections* and their associated costs, *intraluminal thrombotic catheter occlusions* and their associated costs, improve positive patient outcomes and save lives.

Respectfully submitted,

Dana Wm. Ryan
President & CEO

137 Third Avenue North, Franklin, TN 37064 e-mail: dryan@rymedtech.com
website: www.rymedtech.com